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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,550	02/27/2002	Kazuhito Rokutan	ASAM.0051	5577

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EXAMINER	
DEJONG, ERIC S	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/083,550	ROKUTAN ET AL.	
	Examiner	Art Unit	
	ERIC S. DEJONG	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11* is/are pending in the application.

4a) Of the above claim(s) *2-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/2008 has been entered.

Claims 1 and 12 are canceled. Claims 2-11 are pending in the instant application. Claims 2-10 are withdrawn as being drawn to a non-elected species. Claim 11 is currently under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Chenchik et al. (WO 98/53103, see IDS filed 12/15/2004). This rejection is maintained and reiterated from the previous Office action, mailed 05/02/2007.

The instant claim is drawn to an oligonucleotide array consisting of an array of multiple oligonucleotides with different base sequences fixed onto known and separate positions on a support substrate. Said multiple oligonucleotides are limited to biological stress related genes or complementary sequences of said genes. Further, the multiple oligonucleotides are classified according to their gene functions wherein the support substrate has fixation regions divided according to said classification.

Chenchik et al. discloses arrays of polynucleotides and related methods for their preparation and use (see Chenchik et al., Abstract). The disclosed arrays are taught as having a plurality of polynucleotide spots stably associated with the surface of a solid support (see ChenChik et al., page 6, lines 16 and 17). Each spot on an array comprises a polynucleotide probe of known identity (see ChenChik et al., page 6, lines 17-19). Chenchik et al. further teaches that the spots may be arranged in any convenient pattern across or over the surface of the array (see Chenchick et al., page 6, lines 23-27). The substrate of the array comprises at least one surface on which a

pattern of spots may is present, wherein the surface may comprise from about 10 to 5,000 distinct spots of distinct probes (see Chenchik et al., page 6, line 28 through page 7, line 8 and page 8, lines 5-30), which reads on an array of multiple oligonucleotides with different base sequence fixed onto known and separate substrate positions as instantly claimed. Chenchik et al. further sets forth that a critical feature of the arrays is that the polynucleotide spots on an array are made up of polynucleotide probes that all correspond to the same type or kind of gene, i.e. that all genes share some common characteristic or can be grouped together based on some common feature (see especially, Chenchik et al. page 9, lines 11-17), which reads on multiple oligonucleotides with different base sequences fixed onto known and separate positions on said support substrate as well as multiple oligonucleotides classified according to gene function as instantly claimed. Chenchik et al. further teaches that arrays will be of a specific type and further provides specific examples of representative type that include human stress arrays and mouse stress arrays (see Chenchik et al., page 9, lines 24-29), which reads on multiple oligonucleotides that are only biologically stress related genes or complementary sequences to said gene as instantly claimed.

Chenchik et al. also discloses a human stress array wherein all of the unique polynucleotide probe compositions correspond to genes that are associated with stress responses of human cells (see Chenchik et al., page 87). Further, Table 5 sets forth a description and associated activity of all biopolymers sequences used in the polynucleotide spots of a human stress array, which reads on the classification of gene functions (1)-(9) as set forth in lines 7-14 of claim 11. As described above, each distinct

spot on the arrays disclosed by Chenchik et al. comprises distinct a polynucleotide probe of known identity arranged on the surface of the array. Therefore, the human stress array comprising a spots on the disclosed human stress array as set forth by Chenchik et al. reads on a support substrate that has fixation regions divided according to the classification of gene functions as recited in claim 11.

Response to Arguments

Applicant's arguments filed 10/28/2008 have been fully considered but they are not persuasive.

Applicants arguments directed to a rejection under 35 USC 112, second paragraph are moot as there is no grounds of rejection under 35 USC 112, second paragraph applied against the instant claims.

In regards to the rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Chenchik et al., applicants reiterate the argument that Chenchik et al. fails to teach the support substrate has fixation regions divided according to a classification based on gene functions as recited in claim 11.

In response, it is first noted that applicants have not contested the finding that Chenchik et al. teaches the nucleic acid sequences according to gene function (1)-(9) as recited in the instant claims (see Table 5 of Chenchik et al.) nor that Chenchik et al. teaches that these nucleic acid sequences are affixed to an array substrate at distinct locations. It is further reiterated from the instant rejection that each spot on the arrays disclosed by Chenchik et al. comprises distinct a polynucleotide probe of known identity

placed at a known location on the surface of an array. Therefore it is maintained that Chenchik et al. fully and clearly anticipates the instantly claimed array comprising a substrate having fixation regions divided according to a classification based on gene functions (1)-(9) as recited in the instant claim. It is further noted that the instant claims do not specify how an abstract classification of substrate regions results in any structural difference between the claimed array and the arrays set forth in the prior art, since Chenchik et al. clearly teaches that known nucleic acid sequences, encompassed under classifications (1)-(9) as recited in claim 11, are fixed to an array substrate at known and distinct regions.

Applicants further requested that the examiner expressly point to those nucleic acid sequences in Table 5 that meet the classifications (1)-(9) as instantly claims. The following description of the functions of disclosed gene sequences have been directly quoted from Table 5 and the disclosure of Chenchik et al.:

(1) internal and external standard genes for proof reading
(page 9 lines 15-17) teaches The use of “spots” in the pattern drawn to genomic DNA, housekeeping genes, positive and negative controls, and the like”
(page 9, lines 19-21) teaches the use of calibrating or control genes used to establish background or basal levels of expression.

(2) stress related genes related to heat shock protein and hormone genes that decreases under stress
Page 89: M64673, M65217: Heat shock factor proteins
Page 89: D87673, D87673: Heat shock transcription factors

(3) cytokine genes
Page 88: X60188, M84489, X80692, X59727, S38873, U25278, X79483: extracellular signal-regulated kinases

(4) genes that induce cell death
Page 89: U12595, U12596: Tumor Necrosis factor type I receptor associated proteins

(5) genes related to inflammation and wound healing and genes related to cell growth inhibition
Page 94: S40706 (S62138): Growth arrest and DNA-Damage-Inducible Protein GADD153

(6) transcription factor and signaling molecules related to immune response
Page 88: M34356: CREB (Active Transcription factor)
Page 93: M96684: Transcriptional activator protein PUR-alpha

(7) induction of cytokine, which causes cell injury
Page 94: S40706 (S62138): Growth arrest and DNA-Damage-Inducible Protein GADD153

(8) transcription factor and signaling molecules
Page 88: M34356: CREB (Active Transcription factor)
Page 93: M96684: Transcriptional activator protein PUR-alpha

(9) transcription and signaling molecules related to stress response
Page 87: teaches the genes set forth in Table 5 are drawn to a human stress array comprising genes associated with responses of human cell (i.e. stress related)
Page 88: M34356: CREB (Active Transcription factor)
Page 93: M96684: Transcriptional activator protein PUR-alpha

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S DeJong/
Examiner, Art Unit 1631